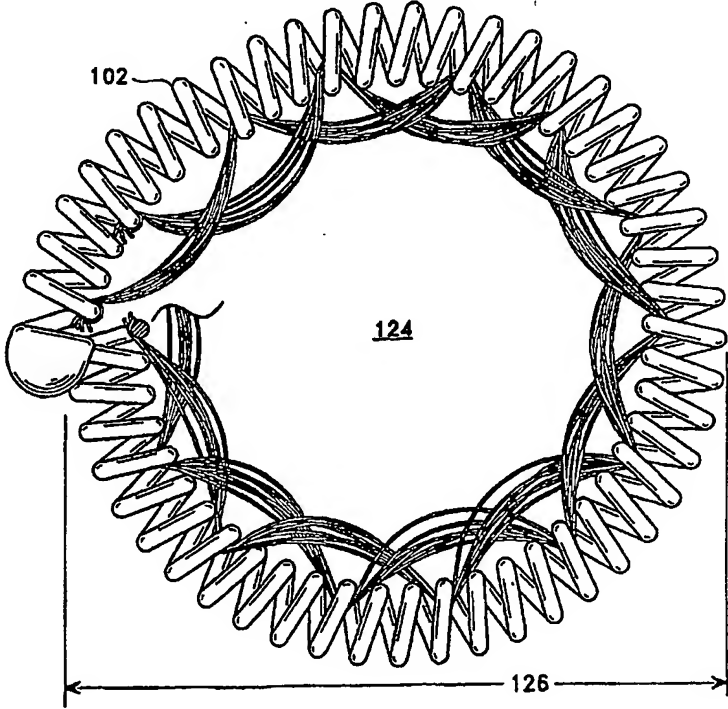




INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

<p>(51) International Patent Classification ⁶ : A61B 17/00</p>	<p>A1</p>	<p>(11) International Publication Number: WO 96/00035 (43) International Publication Date: 4 January 1996 (04.01.96)</p>
<p>(21) International Application Number: PCT/US95/08075 (22) International Filing Date: 21 June 1995 (21.06.95) (30) Priority Data: 08/265,188 24 June 1994 (24.06.94) US (60) Parent Application or Grant (63) Related by Continuation US 08/265,188 (CON) Filed on 24 June 1994 (24.06.94) (71) Applicant (for all designated States except US): TARGET THERAPEUTICS, INC. [US/US]; 47201 Lakeview Boulevard, Fremont, CA 94537-5120 (US). (72) Inventors; and (75) Inventors/Applicants (for US only): MIRIGIAN, Gregory, E. [US/US]; 178 Shaniko Common, Fremont, CA 94539 (US). VAN, Nga, Thi [US/US]; 3583 Mauricia Avenue, Santa Clara, CA 95051 (US). (74) Agents: WHEELLOCK, E., Thomas et al.; Morrison & Foerster, 755 Page Mill Road, Palo Alto, CA 94304-1018 (US).</p>		<p>(81) Designated States: AM, AT, AU, BB, BG, BR, BY, CA, CH, CN, CZ, DE, DK, EE, ES, FI, GB, GE, HU, IS, JP, KE, KG, KP, KR, KZ, LK, LR, LT, LU, LV, MD, MG, MN, MW, MX, NO, NZ, PL, PT, RO, RU, SD, SE, SG, SI, SK, TJ, TM, TT, UA, US, UZ, VN, European patent (AT, BE, CH, DE, DK, ES, FR, GB, GR, IE, IT, LU, MC, NL, PT, SE), OAPI patent (BF, BJ, CF, CG, CI, CM, GA, GN, ML, MR, NE, SN, TD, TG), ARIPO patent (KE, MW, SD, SZ, UG). Published <i>With international search report.</i></p>
<p>(54) Title: VASOOCCLUSIVE COILS WITH THROMBOGENIC ENHANCING FIBERS</p> <p>(57) Abstract</p> <p>This invention is a vasoocclusive device (100). It is placed in the vasculature of an animal to form a thrombus in a selected site such as an aneurysm or AVM. The device uses a central coil (102) having thrombogenic fibers (104, 106) placed on the coil in a specified fashion. The coil will pass through the lumen of a vascular catheter and form a convolution when ejected from the catheter's distal end. The fibers are attached to the coil and cooperate with the coil so that upon ejection from the catheter, the convoluted coil forms a shape in which the central region contains the majority of these fibers.</p> 		

FOR THE PURPOSES OF INFORMATION ONLY

Codes used to identify States party to the PCT on the front pages of pamphlets publishing international applications under the PCT.

AT	Austria	GB	United Kingdom	MR	Mauritania
AU	Australia	GE	Georgia	MW	Malawi
BB	Barbados	GN	Guinea	NE	Niger
BE	Belgium	GR	Greece	NL	Netherlands
BF	Burkina Faso	HU	Hungary	NO	Norway
BG	Bulgaria	IE	Ireland	NZ	New Zealand
BJ	Benin	IT	Italy	PL	Poland
BR	Brazil	JP	Japan	PT	Portugal
BY	Belarus	KE	Kenya	RO	Romania
CA	Canada	KG	Kyrgyzstan	RU	Russian Federation
CF	Central African Republic	KP	Democratic People's Republic of Korea	SD	Sudan
CG	Congo	KR	Republic of Korea	SE	Sweden
CH	Switzerland	KZ	Kazakhstan	SI	Slovenia
CI	Côte d'Ivoire	LI	Liechtenstein	SK	Slovakia
CM	Cameroon	LK	Sri Lanka	SN	Senegal
CN	China	LU	Luxembourg	TD	Chad
CS	Czechoslovakia	LV	Latvia	TG	Togo
CZ	Czech Republic	MC	Monaco	TJ	Tajikistan
DE	Germany	MD	Republic of Moldova	TT	Trinidad and Tobago
DK	Denmark	MG	Madagascar	UA	Ukraine
ES	Spain	ML	Mali	US	United States of America
FI	Finland	MN	Mongolia	UZ	Uzbekistan
FR	France			VN	Viet Nam
GA	Gabon				

5 VASOOCCLUSIVE COILS WITH THROMBOGENIC ENHANCING FIBERS

Field of the Invention

This invention is a vasoocclusive device. It
10 is placed in the vasculature of an animal to form
thrombus in a selected site such as an aneurysm or AVM.
The device uses a central coil having thrombogenic fibers
placed on the coil in a specified fashion. The coil will
pass through the lumen of a vascular catheter and form a
15 convolution when ejected from the catheter's distal end.
The fibers are attached to the coil and cooperate with
the coil so that upon ejection from the catheter, the
convoluted coil forms a shape in which the central region
contains the majority of these fibers.

20

Background of the Invention

Vasoocclusive devices are surgical implants
placed within blood vessels or vascular cavities,
typically by the use of a catheter, to form a thrombus
25 and occlude the site. For instance, treatment of a
stroke or other such vascular accident may include the
placement of a vasoocclusive device proximal of the site
to block the flow of blood to the site and alleviate the
leakage. An aneurysm may similarly be treated by
30 introduction of a vasoocclusive device through the neck
of the aneurysm. The thrombogenic properties of the
vasoocclusive device causes a mass to form in the
aneurysm and alleviates the potential for growth of the
aneurysm and its subsequent rupture. Other diseases,

35

such as tumors, may often be treated by occluding the blood flow to the tumor.

There are a variety of vasoocclusive devices suitable for forming thrombus. One such device is found
5 in U.S. Patent No. 4,994,069, to Ritchart et al., the entirety of which is incorporated by reference. That patent describes a vasoocclusive coil that assumes a linear helical configuration when stretched and a folded convoluted configuration when relaxed. The stretched
10 configuration is used in placement of the coil at the desired site and the convoluted configuration occurs when the coil is ejected from the catheter and the coil relaxes.

There have been increasing needs to increase
15 the inherent thrombogenicity of these devices. One way of increasing that thrombogenicity is to increase the amount of fiber found in the device. U.S. Patent No. 5,226,911, to Chee et al., describes a vasoocclusive coil with attached fibrous elements. The fibers are looped in
20 a generally serpentine manner along the coil. The fibrous loops are affixed to (or looped through) the coil at spaced intervals along the coil. The use of multiple fibrous windings is noted in the patent but that use is said to involve placement of the fibers 180° apart on the
25 circumference of the coil.

It should be noted that additional filaments on the exterior of the coil increase the friction of the fibrous coil against the catheter lumen. Added filaments increase the desired thrombogenicity. It is this balance
30 which is difficult to make. We have found a way to increase the overall thrombogenicity without substantially affecting the friction of the inventive coil against the deployment catheter.

Brief Description of the Drawings

Figure 1 shows a partial side view of a typical coil (expanded) made according to the invention.

5 Figure 2 shows a partial side view of the inventive coil showing details of fiber attachment.

Figure 3 shows a partial side view schematically depicting the attachment of multiple filamentary elements.

10 Figure 4 shows a cross section, end view of the inventive coil showing placement of the filamentary elements.

Figures 5A and 5B are fragmentary cross-sections of end sections of the inventive fibered coils.

15 Figure 6 shows a plan view of the relaxed inventive coil after deployment.

Description of the Invention

As has been noted above, this invention is a vasoocclusive device and, in particular, it is a fibered coil.
20

Figure 1 shows a length of the fibered coil (100). It is made of several components: a helical coil (102), a first fibrous element (104), and a second fibrous element (106). The end of the coil may be sealed to form a cap (108).
25

The helical coil (102) is typically of a radiopaque material such as tungsten, tantalum, gold platinum, and alloys of those materials. Stainless steels are also suitable. The use of various polymers, such as polyethylene, polyurethane, and the like as the coil material is also contemplated. The use of polymeric materials typically involves the use of known radiopaque fillers such as powdered tantalum, powdered tungsten, barium sulfate, bismuth oxide, bismuth carbonate, or the like. Preferred, however, is an alloy of platinum with a
30
35

minor amount of tungsten. This alloy is very flexible and yet the tungsten takes away a measure of ductility from the resulting coil.

5 The coil may be from 0.2 to 100 cm in length or more. The diameter of the coil is from 0.004" to 0.015", typically from 0.008" to 0.012". The wire making up the coil is 0.0005" to 0.002" in diameter. The coil may be wound to have a tight pitch, that is to say, that there is no space between the adjacent turns of the coil, or it
10 may have some space between adjacent turns. Most desirable, from the point of view of having a high content of fiber, is a coil which is slightly stretched in the manner and in the amount described below.

The first (104) and second (106) fibrous
15 elements typically are bundles of individual fibers (5 to 100 fibers per bundle), but may be individual fibers. The fibers may be of a number of different thrombogenic materials. Suitable synthetic fibers include polyethylene terephthalate (e.g., DACRON), polyesters,
20 especially polyamides (e.g., the Nylons), polyglycolic acid, polylactic acid, and the like. Other less desirable synthetic polymers, because of their decreased thrombogenicity, include fluorocarbons (Teflon) and polyaramids (Kevlar). Natural fibers such as silk and
25 cotton are also quite suitable.

The fibered coil (100) shown in Figure 1 is in the general shape as found in the catheter lumen. The coil (102) has been stretched to place the first fibrous element (104) and second fibrous element (106) close
30 along the outer periphery of the coil (102). This stretching lessens the overall diameter of the fiber coil (100) as seen by the catheter lumen.

As may be seen more clearly in Figure 2, the multiple fiber elements are alternately looped along the
35 coil. That is to say that the looping of the first fiber

element (104) through coil (102) alternates with the looping of the second fiber element (106) through coil (102). The fiber elements may be looped through the coil (102) as shown in Figures 1 and 2 or they may be tied at intersections with the coil (106) although, because of the interference between the knot end catheter offered by the knot, a mere looping is preferred. The end passage of the fibers through the coil desirably involves a knot. Only a pair of fibrous elements (104 and 106) are shown in Figures 1 and 2; multiple such fiber elements may be used, however. Additionally, it is quite desirable that the spacing of the fibrous elements as they cross the coil need not be equal.

As is portrayed in the side view found in Figure 3, multiple filament numbers having a short coil spacing (110), an intermediate coil spacing (112), and a long coil spacing (114). These various fiber spacings tend to increase the randomness of the fibered center of the randomized coil after it is released from the catheter. This benefit will be discussed in more detail below.

A significant aspect of this invention is shown in Figure 4. That drawing, a cross-section view, shows that the various fiber elements (in this example, 104 and 106) occupy a small radial sector of the coil's circumference. Although, upon deployment, the various fiber elements will shift toward each other to a modest degree, the filaments must be placed in the same 90° quadrant (105) to attain maximum benefit of the invention. This quadrant is measured perpendicularly to the axis of the stretched coil.

Finally, Figure 1 shows an end (108) on coil (102). Such ends (108) are typically produced by heating the end of the coil (102) to melt a small section of the

coil and form a closed end (108). Figure 5A shows a close-up of the end (108) and the coil (102).

Figure 5B shows an additional variation in which the coil (102) encompasses a control wire (116) and an end cap (118) having a hole therethrough. Use of such a control wire (116) allows "ganging" of the coils or placement of a number of coils "nose-to-tail" within the catheter and therefore gives the attending surgeon the choice of using one or more coils without reloading the catheter.

Figure 6 shows the shape of the coil (102) after it has been deployed from the catheter. The coil (102) encompasses an interior region (124) which has fiber passing through the region which is formed by creation of a secondary diameter (126). This region (124) of fibers provides for additional thrombogenicity in the open region (124) among the secondary coil (126) turns. This added and widely spaced fiber results in an enhanced thrombus formation rate - typically a matter of concern in using these devices for treatment of vascular problems. We have found that by use of this procedure of fiber attachment, upwards of 65% of the fibers found on the coil are introduced into the open region (124), preferably more than 75% and, most preferably, more than 85%.

The coils (102) discussed above are "preformed" so as to allow the coil (102) to assume the secondary diameter (126) shown in Figure 6. The patent to Ritchart et al. (U.S. Patent No. 4,994,069), discussed above, discusses a number of ways to preform such coils, e.g., by crimping the coil at various intervals. Another way to preform the coils, particularly when using the preferred platinum/tungsten alloy mentioned above is by winding the coil on a mandrel into the secondary diameter shown in Figure 6 and then modestly heat-treating the

thusly-wound coil. The coil will retain sufficient flexibility to extend, in a linear fashion, through a catheter lumen.

5 This device may be deployed in the same manner as are the coils described in the Ritchart et al or Chee et al patents discussed above. In general, a vascular catheter is introduced into the bloodstream at a convenient site, often the femoral artery in the groin, and advanced to the site of concern. As has been noted
10 elsewhere, these sites are often in the cranial arteries but may be in any other site where occlusion is desired. Guidewires are typically used to direct the catheter to the desired site but blood flow is used to direct flow-directed catheters. Once the distal end of the catheter
15 is at the site, the catheter lumen is cleared of guidewires and the like. The inventive coil is then introduced into the lumen, often with the help of a cannula to preserve the shape of the elongated coil until it enters the catheter lumen. A pusher, typically
20 similar in shape to a guidewire is then introduced into the catheter lumen to push the inventive coil along the interior of the catheter and out its distal end. Once the coil is safely in place, the catheter is removed from the body.

25 This invention has been described using specific details to augment the explanation of that invention. However, it is not our intent that the specifics so used would be in any manner limiting to the
30 claimed invention. It is our intent that variations of the invention which would be considered equivalent to one having ordinary skill in this art be within the scope of the claims which follow.

35

WE CLAIMS AS OUR INVENTION:

1. A vasoocclusive device comprising:
 - (a) a helical coil having windings extending
5 between a first end and a second end,
 - (b) a first fibrous element having a first end
and a second end, with the portion of the
first fibrous element between these ends
10 extending axially along the coil and
having discrete sections defined by
threading said first fibrous element about
a winding at intervals along said helical
coil, and
 - (c) at least one supplemental fibrous element
15 having a first end and a second end, with
the portion of the supplemental fibrous
element between those ends extending
axially along the coil and having discrete
sections defined by threading said
20 supplemental fibrous element about a coil
winding at intervals along said helical
coil different than said first fibrous
element.
- 25 2. The vasoocclusive device of claim 1
wherein at least one supplemental fibrous element
comprises one fibrous element.
- 30 3. The vasoocclusive device of claim 2
wherein the supplemental fibrous element comprises
intervals longer than the first fibrous element.
- 35 4. The vasoocclusive device of claim 1
wherein the helical coil has an axis between the first
end and the second end and said first and supplemental

fibrous elements are threaded through the helical coil in a quadrant measured perpendicular to the coil axis.

5 5. The vasoocclusive device of claim 1
wherein the fibers are selected from silk, cotton,
polyethylene terephthalate, polylactic acid, polyglycolic
acid, polyesters, fluorocarbons, and polyaramids.

10 6. The vasoocclusive device of claim 5
wherein the fibers are polyethylene terephthalate.

15 7. The vasoocclusive device of claim 1
wherein the coil is preformed to form a secondary form
after it is relaxed.

20 8. The vasoocclusive device of claim 7
wherein the coil is preformed to form a secondary form
after it is relaxed and more than about 65% of the first
fibrous element and at least one supplemental fibrous
element reside within the secondary form after the coil
is relaxed.

25 9. The vasoocclusive device of claim 7
wherein the coil is preformed to form a secondary form
after it is relaxed and more than about 85% of the first
fibrous element and at least one supplemental fibrous
element reside within the secondary form after the coil
is relaxed.

30

35

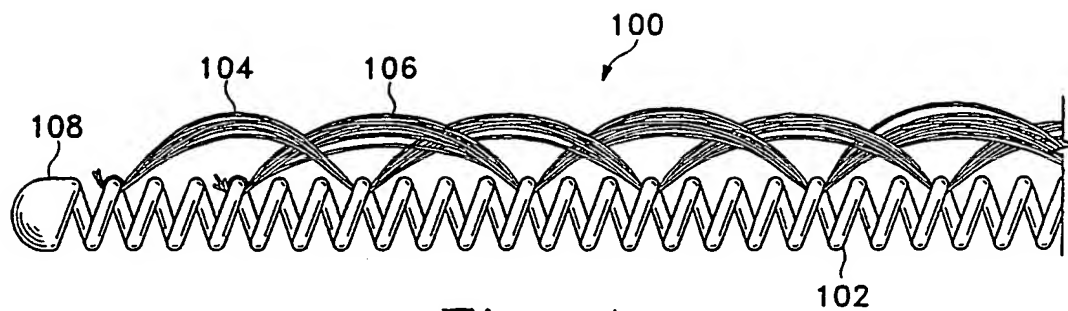


Fig. 1

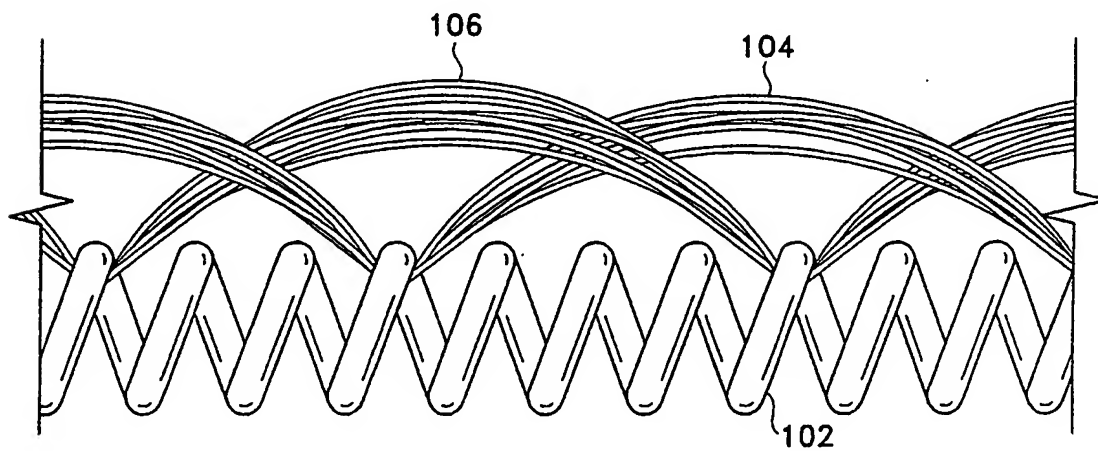


Fig. 2

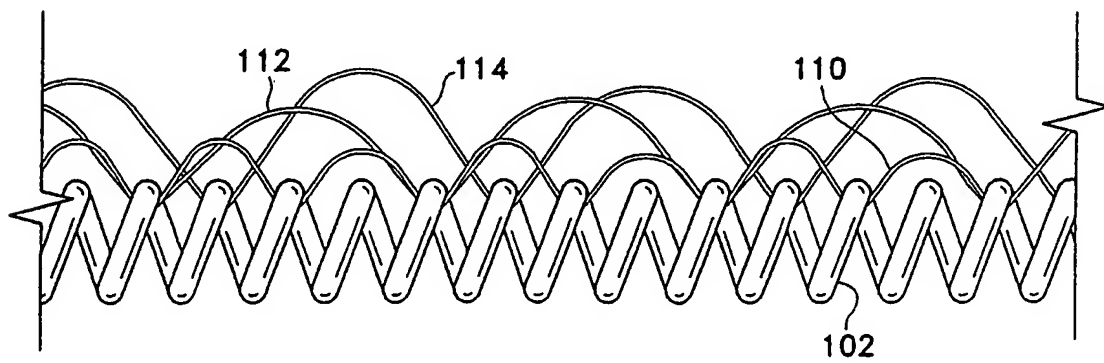


Fig. 3

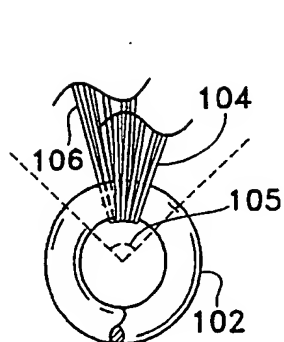


Fig. 4

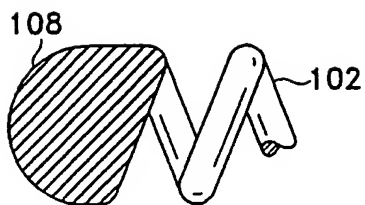


Fig. 5A

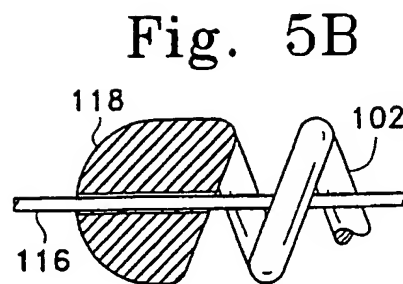


Fig. 5B

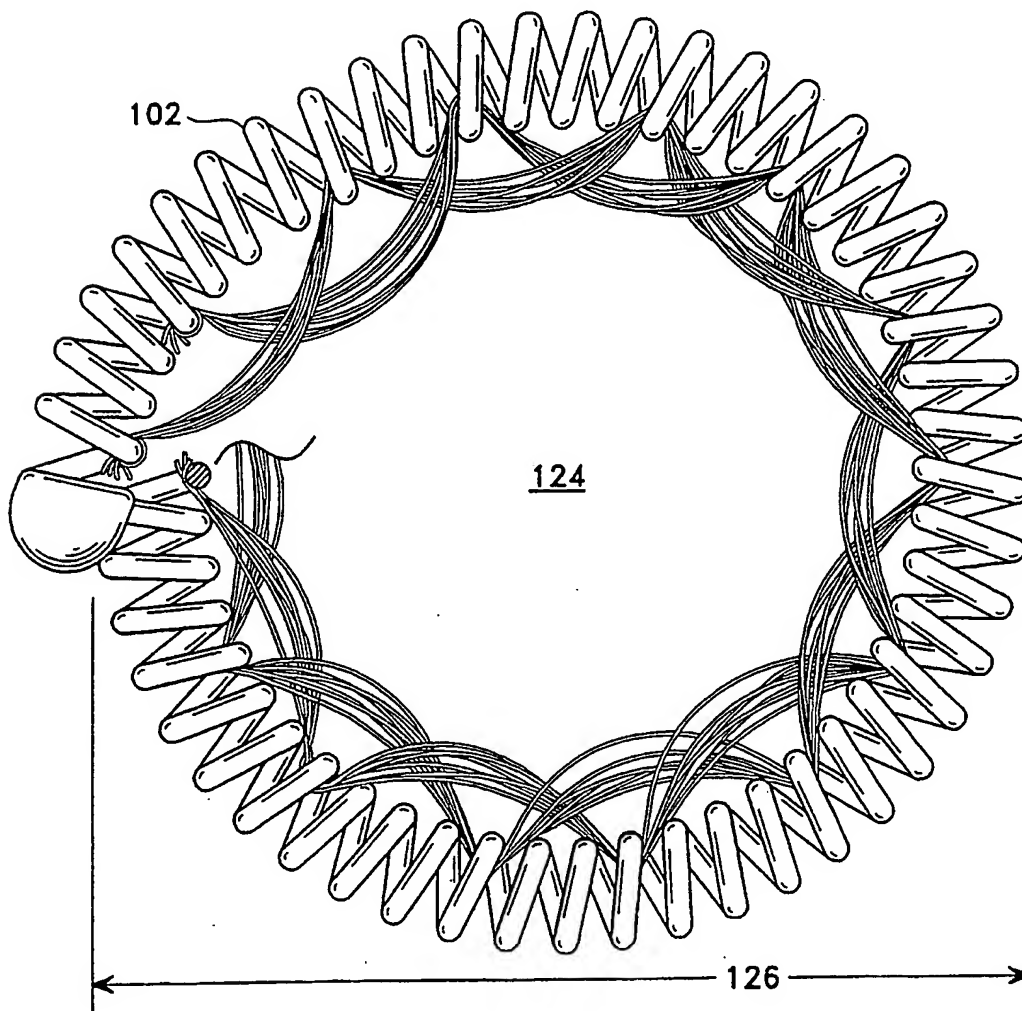


Fig. 6

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US95/08075

A. CLASSIFICATION OF SUBJECT MATTER IPC(6) :A61B 17/00 US CL :606/191; 623/11 According to International Patent Classification (IPC) or to both national classification and IPC		
B. FIELDS SEARCHED Minimum documentation searched (classification system followed by classification symbols) U.S. : 606/1, 108, 151, 190-198; 623/1, 11, 12 Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched NONE Electronic data base consulted during the international search (name of data base and, where practicable, search terms used) NONE		
C. DOCUMENTS CONSIDERED TO BE RELEVANT		
Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	US, A, 4,994,069 (RITCHART ET AL.) 19 February 1991, see entire document.	1-9
X	US, A, 5,304,194 (CHEE ET AL.) 19 April 1994, see entire document.	1-7
<input type="checkbox"/> Further documents are listed in the continuation of Box C. <input type="checkbox"/> See patent family annex.		
* "A" "E" "L" "O" "P"	Special categories of cited documents: document defining the general state of the art which is not considered to be part of particular relevance earlier document published on or after the international filing date documents which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified) document referring to an oral disclosure, use, exhibition or other means document published prior to the international filing date but later than the priority date claimed	"T" "X" "Y" "&" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art document member of the same patent family
Date of the actual completion of the international search 12 SEPTEMBER 1995		Date of mailing of the international search report 22SEP1995
Name and mailing address of the ISA/US Commissioner of Patents and Trademarks Box PCT Washington, D.C. 20231 Facsimile No. (703) 305-3230		Authorized officer <i>Stacia Simcik</i> GLENN KEITH DAWSON Telephone No. (703) 308-4304 <i>for</i>